

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Judith McInally et al. Art Unit : 1626  
Patent No. : 7,605,159 Examiner : Rebecca L. Anderson  
Issue Date : October 20, 2009 Conf. No. : 3793  
Serial No. : 10/538,452  
Filed : June 10, 2005  
Title : CATHEPSIN CYSTEINE PROTEASE INHIBITORS AND THEIR USE

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 434 days to 754 days is respectfully requested.

**REMARKS**

(1) Measuring Overlap of “A Delay” and “B Delay”

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in *Wyeth et al. v. Jon W. Dudas* (580 F. Supp. 2d 138; 88 USPQ 2d 1538), the only way that these periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as calculated by the PTO and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) before the initial three-year period expired. The *Wyeth v. Dudas* court

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I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: December 17, 2009.

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determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” “B delay” begins only after, not before, the PTO has failed to issue a patent within three years. *Id.*

## (2) Measuring “B Delay” for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the “overlap” issue addressed above, Patentees respectfully submit that the Office did not apply the proper standard for determining the period of “B Delay” under 35 U.S.C. § 154(b)(1)(B). It is Patentees’ understanding that for purposes of calculating “B Delay,” the Office measured application pendency as beginning on June 10, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371.

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the “actual filing date” of the application.

### (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION

PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term “actual filing date” as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins if the Office fails to issue a patent within three years after the date the national stage “commenced under 35 U.S.C. 371(b) or (f).”<sup>1</sup>

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application,

<sup>1</sup> Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that “[i]n the case of an international application, the phrase ‘actual filing date of the application in the United States’ [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f).”

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but not including... 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences."

(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

#### REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

##### "A Delay"

A first PTO action was due on or before August 10, 2006 (the date that is fourteen months after June 10, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on January 16, 2008, thereby according a PTO Delay of 524 days. Patentees do not dispute the PTO's calculation for this "A Delay" from August 11, 2006 (the day after August 10, 2006), to January 16, 2008. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as 524 days.

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### “B Delay”

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/SE2003/001931, filed December 13, 2003, which claims the benefit of priority of Sweden application number 0203712-5, filed December 13, 2002.

When the present application was, Patentees filed a complete request for early processing under 35 U.S.C. § 371(f). Thus, the national stage for the present application “commenced” under the provisions of 35 U.S.C. § 371(f), i.e., upon express request for processing of the application and upon compliance with all the applicable requirements of 35 U.S.C. § 371(c). As a result, the date that the national stage commenced was June 10, 2005.

The period beginning on June 11, 2008 (the day after the date that is three years after June 10, 2005, the date that the national stage commenced), and ending October 20, 2009 (the date the patent was issued), is 497 days in length.

“B Delay” may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). In the present application, a Request for Continued Examination was filed on April 27, 2009, and the patent issued on October 20, 2009, which resulted in a period of 177 days that must be excluded from the three year delay calculation.

In addition, “B Delay” may not include the number of days in the period beginning on the date on which a Notice of Appeal was filed and ending on the date of mailing of a Notice of Allowance. See 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4). In the present application, no Notice of Appeal was filed.

In view of the periods of “B Delay” detailed above, the total “B Delay” for this patent should be calculated as 320 days (i.e., 497 days minus 177 days). By contrast, the PTO erroneously granted 0 days of delay for issuance of a patent more than three years after filing. Patentees respectfully submit that the PTO’s grant of this “B Delay” is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 320 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

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#### Overlap of “A Delay” and “B Delay”

As detailed above, “A Delay” accumulated during the following period:

August 11, 2006, to January 16, 2008.

As detailed above, “B Delay” accumulated during the following period:

June 11, 2008, to April 27, 2009.

As such, the periods of “A Delay” and “B Delay” do not overlap (i.e., occur on the same calendar day).

#### Applicant Delay

A reply to an Office Action was due on or before January 27, 2009 (the date that is three months after October 27, 2008, the mailing date of the Office Action). Patentees filed a response to the Office Action on April 27, 2009, thereby according an Applicant Delay of 90 days.

Patentees do not dispute the PTO’s calculation for this Applicant Delay from January 28, 2009 (the day after January 27, 2009) to April 27, 2009. See 37 C.F.R. § 1.704(b).

In view of the periods of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 90 days.

#### Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

#### Conclusion

In consideration of the events described above, Patentees believe the PTA calculation of 434 days is incorrect. As such, Patentees respectfully request reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 844 days (i.e., the sum of 524 days of “A Delay” and 320 days of “B Delay”);
- 2) Total Applicant Delay should be calculated as 90 days; and
- 3) Total PTA should be calculated as 754 days.

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The fee of \$200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges to Deposit Account No. 06-1050, referencing Attorney's Docket No. 06275-0455US1.

Respectfully submitted,

Date: December 17, 2009

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